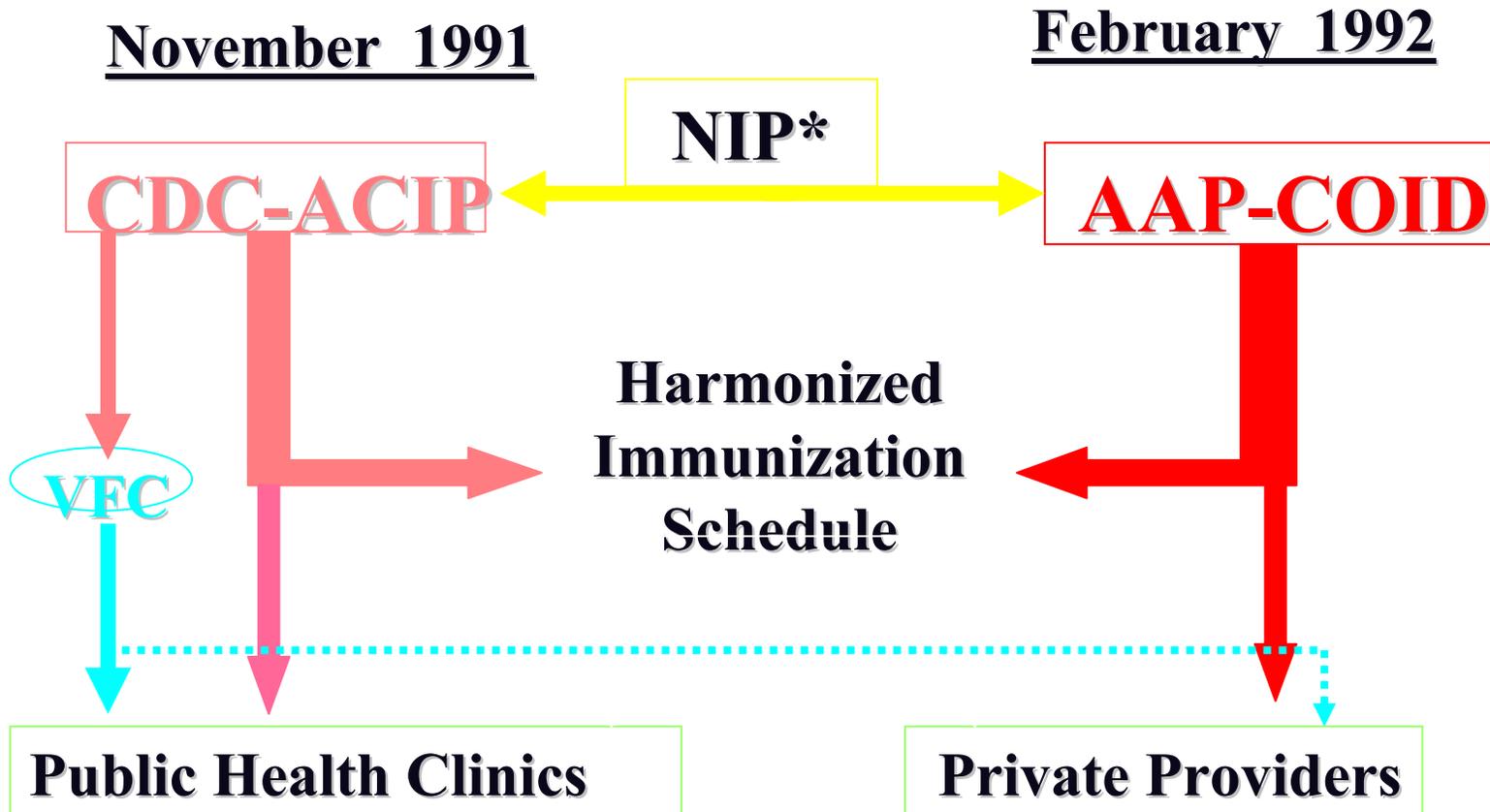


**The First International
Neonatal Vaccination Workshop
March 2- 4, 2004**

**Neonatal Vaccination in the United States:
Implementation of the Hepatitis B Birthdose**

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Coordinating Neonatal Hepatitis B Immunization Recommendations in the United States.



* National Immunization Program

STATE IMMUNIZATION PROGRAMS

Where the Action Is

50 State Immunization Programs

(17 Universal Purchase: 33 VFC Hybrids*)

+

27 Urban Immunization Districts

+

District of Columbia

*** Vaccines For Children government source vaccine for qualified children**

Immunization Centers

- **SMALL OFFICE SETTING**
- **LARGE CLINICS / MANAGED CARE**
- **PUBLIC HEALTH CLINICS**
- **HOSPITALS ??????**

Regional Hospital Implementation of Universal Infant Hepatitis B Immunization (1993)

| <u>Regional Term Nurseries in the United States:</u> | <u>% routinely offering HBV vaccination before D/C</u> | |
|---|---|--------------------|
| Northeast | 47% | |
| South | 53% | |
| Midwest | 58% | |
| West | 31% | |
| | | (p= NS) |
| Hospitals with a NICU | 52% | |
| Hospitals without a NICU | 31% | |
| | | (p=0.075) |

Kim SC, Sinai LN et al. Pediatrics. 1995; 95: 764-66

Preparing Wisconsin Hospital Systems for the Hepatitis B Immunization of Neonates (1993)

- **Mission:** Three front attack on hepatitis B to prevent vertical, horizontal and community transmission.
- **Economics:** Vaccine at clinic prices.
- **Informed Consent:** Need for birthing staff advocacy.
- **Standing Orders:** All clinical scenarios including infants born to HBsAg (+), (-) and (?) mothers.
- **Documentation:** Mother's HBsAg status, infant's receipt of vaccine
- **Physician Notification:** Vaccination given in hospital
- **Immunization Card Distribution:** Before infant leaves the hospital

Wisconsin Birthing Hospital Survey of Compliance with Program Elements (1993)

- **99%** give HBV literature to parents and document HBV administration on infant's record
- **89%** require informed consent
- **88%** have method to notify attending M.D. their infant was given HBV vaccine
- **85%** have standing orders to give infants HBV
 - **81%** have orders specifying immunizing infants of HBsAg (-) and HBsAg (+) mothers
 - **68%** specify orders to immunize infants with mother's of unknown HBsAg status
 - **38%** have standing orders to test mothers with unknown HBsAg status

Hurie MB, Saari TN et al. Pediatrics 1995; 96: 875-79

Wisconsin Hepatitis B Hospital Survey: 1993

- 71 (65%) of 110 hospitals with delivery services offer HBV vaccine to all infants representing 80% of all Wisconsin births
- *Regional morbidity* does not influence decision to start a hospital based program. Rural hospitals are no less likely to immunized neonates than urban centers.
- *Hospital size* is not a factor in starting a HBV program.
- Hospitals claim vaccine *Cost* is not an issue.
- *MD staff perception* of need for vaccination in infants dictates the development of a hospital based program

Hurie MB, Saari TN et al. Pediatrics 1995; 96: 875-79

Convincing Physicians to Initiate Hepatitis B Birthdosing

- **Does Local Anecdotal Experience with hepatitis B reflect the Urgency of National Advisory Group Recommendations?**
- **Do Vaccine Benefits exceed Vaccine Shortcomings?**
- **What is the Economic Impact on the Practice Bottom Line?**
- **What are Colleagues in the Community going to Do?**
- **Will the Parents Accept the Clinical Rationale and the Additional Injections that this Recommendation entails?**

Playing Percentages with Providers

30% will accept AAP / ACIP recommendations and implement them ASAP

60% will weigh the pros and cons of the recommendations to their practice, the cost of implementing, check what the competition is doing and let someone else discover the rare adverse events before offering the vaccine (2 to 5 year process)

10% the “ conspiratorial “ 10% who believe the AAP and the CDC are in an unholy alliance with greedy drug companies by pushing a unnecessary vaccine of questionable virtue.

Physician Acceptance of Universal Infant Hepatitis B Immunization (1992-3)

| <u>Pediatrician Surveys</u> | <u>Time After Recommendation Release</u> | <u>Agrees with Universal Infant HBV vaccination</u> |
|----------------------------------|--|---|
| Freed et al. Peds. 1993: 91: 699 | 3 months | 32% |
| CDC/AAP. Vacc. Bull. 1993; Sept. | 1 year | 50% |
| Freed et al. Peds 1994; 93: 747 | 1 year | 66% |
| Kim et al. Peds. 1995;95: 764 | 2. 5 years | 85% |

Barriers:

- My patient is not at risk
- Cost and cost effectiveness
- Parents will object to another injection in newborn period
- Parents will not accept the clinical rationale of risk and global disease control
- Vaccine safety
- Waning immunity and possible need for subsequent booster.

The Benefits of Routine Newborn Hepatitis B Vaccination

- Only vaccine that prevents **cancer**.
- Only vaccine that is reliably immunogenic in the **neonate**.
- An opportunity to immunize during one of the few **dependable medical encounters**.
- The best opportunity to prevent **unrecognized** perinatal spread and to prevent **horizontal** spread within households with other family members who have silent chronic carriage.
- Places the importance of immunization as an early and visible **priority** for parents.
- Added insurance that an overall immunization series will be **completed on time**.
- The foundation of the overall **strategy to eliminate hepatitis B** in the US and globally.
- The Wisconsin Department of Health provides **free HBV vaccine** to every newborn, regardless of payor status.

Hepatitis B Vaccine Use in Wisconsin: 1998

| I currently give HBV vaccine: | Madison | Milwaukee | Average | State |
|----------------------------------|---------|------------------|-------------------|------------|
| 1) Before hospital D/C | 75% | 49% | 68% | |
| 2) At 2 weeks old | 25% | 15% | 16% | |
| 3) By 2 months old | 100 % | <u>0%</u> 98% | <u>34%</u> 99% | <u>15%</u> |
| 4) All children Birth - 19 yr | 89% | 73% | 79% | |

Wisconsin pediatrician survey: April ' 98

127 responses of 208 Wisconsin pediatricians polled (61%)

Infant Hepatitis B Birth-dosing Study of All 98 Wisconsin Birthing Hospitals

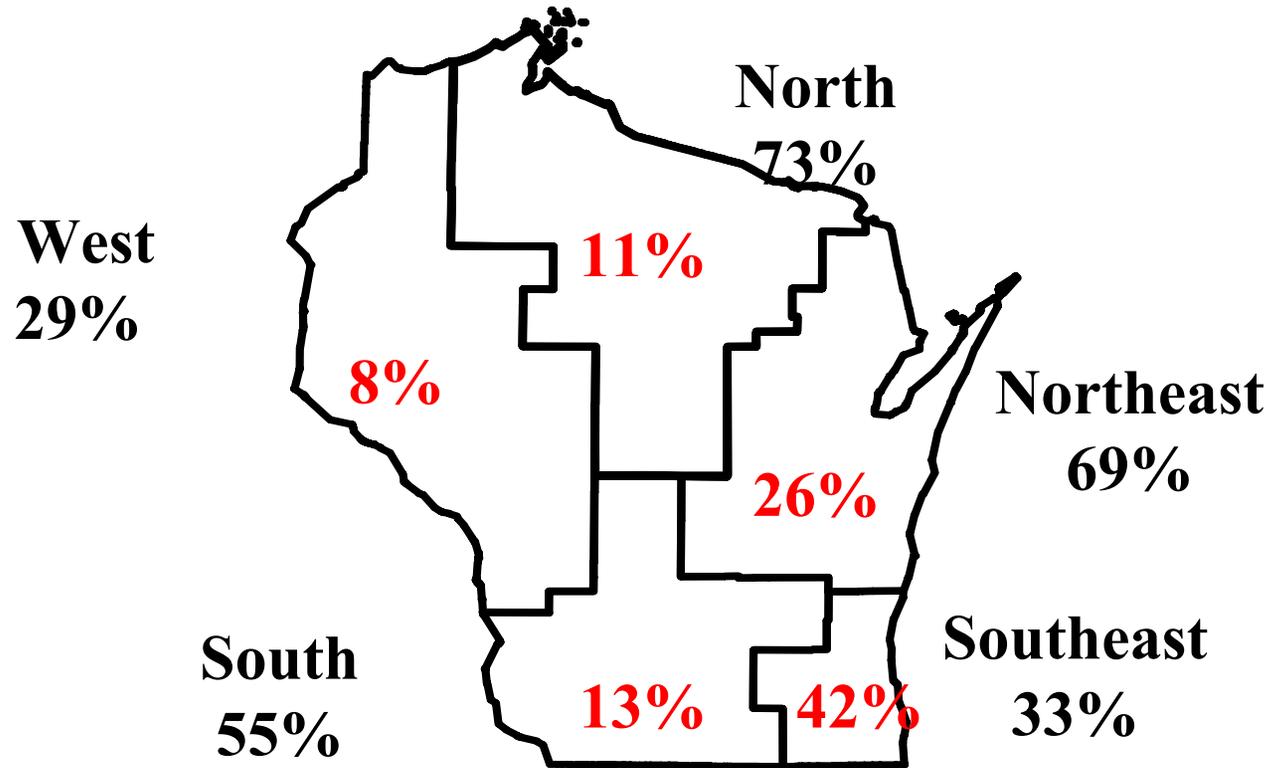
(Before and After the Thimerosal Controversy)

| <u>Hospital Policy*</u> | <u>July 1999</u> | <u>March 2000</u> |
|---|------------------|-------------------|
| Most infants offered before discharge | 80% | 48% |
| Infants offered HBV at discharge | 53,186 | 27,477 |
| Total birth cohort \cong 65,000 | | |

* 98 of 98 Birthing Hospitals in Wisconsin responded to a survey completed 4/00

Hurie MB, Saari TN, Davis JP. Pediatrics.2001;107: 755-8.

Percent of Wisconsin Hospitals Offering Hep B vaccine to Infants Prior to Hospital Discharge: 2 / 2000



Percent of 201 Wisconsin HBsAg (+) Pregnant Women delivering infants in 2000

Hurie MB, Saari TN, Davis JP. *Pediatrics*.2001;107: 755-8.

**Infant Hepatitis B Birth-dosing in Wisconsin Hospitals:
(Before and After the Thimerosal Controversy)**

| <u>Health District:</u> | <u>July '99</u> | <u>March ' 00</u> | <u>% Change</u> |
|-------------------------|-----------------|-------------------|-----------------|
| • Northern | 77% | 73% | - 5 |
| • Western | 33% | 29% | -12 |
| • Southern | 63% | 55% | -13 |
| • Northeastern | 92% | 69% | -25 |
| • Southeastern | 68% | 32% | -53 |

**If HBV is offered at your hospital,
what percentage of infants receive the vaccine? = 51%**

Hurie MB, Saari TN, Davis JP. Pediatrics.2001;107: 755-8.

Wisconsin Hospital Policies for Routine Hepatitis B Birthdosing (1993-2003)

ALL INFANTS

7/ 1999* 8/ 1999^ 3/ 2000 ^ 7/2003@

Hospitals (# Births)

| | | | | |
|---------------------------|------------|------------|------------|------------|
| Overall | 81% | 48% | 54% | |
| Small (<500) | 55% | | 55% | |
| Medium (500-999) | 76% | | | 47% |
| Large (>1000) | 82% | | 64% | |

INFANTS OF:

| | | | |
|-------------------------|------------|------------|------------|
| HBsAg + Moms | 70% | 93% | 93% |
| HBsAg (?) Moms | 41% | 74% | 83% |

* Hurie MB, Saari TN et al. *Pediatrics* 1995; 96: 875-79

^ Hurie MB, Saari TN, Davis JP. *Pediatrics*.2001;107: 755-8.

@ Russell A, Saari TN, Davis JP. 2004 in press

Identifying Barriers in Private Practice to Neonatal Vaccination in Wisconsin (2003)

Reason:

Percent

- | | |
|--|-----|
| • Physician preference to start hepatitis B series in the office at 2 wks to 2 months of age | 57% |
| • All mothers/infants at risk are known | 22% |
| • Prefer a HBV – HiB combination vaccine given at 2 months of age | 20% |
| • Hepatitis B not a problem in our community | 9% |
| • Vaccine cost concern in hospital | 9% |
| • Concern about thimerosal in vaccines | 7% |
| • Our infants are at no risk from household HBV chronic carriers | 7% |

The Prospects for Neonatal Immunization in the United States

- 1. For hospitals to provide routine neonatal vaccination, they will require an intensive public health acculturation process along with infrastructure improvements to be efficient immunizers.**
- 2. For physicians to be strong advocates of neonatal vaccination, a lengthy preparatory phase may be needed depending on the vaccine used, its cost / benefit and adverse event profile and its clinical relevance to the experience of the practitioner.**
- 3. For parents to accept the prospect of their newborn receiving vaccinations, they must be convinced of the clinical benefit and the safety of the vaccine offered (see # 2).**